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Der Präsident des Europäischen Patentamts;
Im Auftrag

For the President of the European Patent Office

Le Président de l'Office européen des brevets
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Böhm, Stephan, Dr.
Kegelhofstrasse 22
20251 Hamburg
ALLEMAGNE

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Method and apparatus for controlling at least one ventilation pressure of an artifical ventilator for ventilating the lung of a patient lying in a rotation bed

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Stephan Böhm, Kegelhofstr. 22, 20251 Hamburg

Method and apparatus for controlling at least one ventilation pressure of an artificial ventilator for ventilating the lung of a patient lying in a rotation bed

The invention refers to a method and an apparatus for controlling at least one ventilation pressure of an artificial ventilator for ventilating the lung of a patient lying in a rotation bed in accordance with a rotation angle of the rotation bed around its longitudinal axis. Furthermore, the invention refers to a method and an apparatus for determining the status of the lung of a patient lying in a rotation bed in accordance with a rotation angle of the rotation bed around its longitudinal axis and to a method and an apparatus for controlling the rotation angle of a rotation bed around its longitudinal axis.

The treatment of acute lung failure, acute lung injury (ALI) and acute respiratory distress syndrome (ARDS) is still one of the key problems in the treatment of severely ill patients in the intensive care unit. Despite intensive research over the past two decades the negative implications of respiratory insufficiency are still affecting both the short and long term outcome of the patient. While different ventilator strategies have been designed to treat the oxygenation disorder and to protect the lungs from ventilator induced lung injury, additional therapeutic options were evaluated.

Body positioning (kinetic or axial rotation therapy) was first described by Bryan in 1974. This technique is known to open atelectasis and to improve lung function, particularly arterial oxygenation in patients with ALI and ARDS. Since kinetic therapy is a non-invasive and relatively inexpensive method it can even be used prophylactically in patients whose overall health condition or severity of injury predispose to lung injury and ARDS. It could be shown that the rate of pneumonia and pulmonary complications can be reduced while survival increased if kinetic therapy is started early on in the course of a ventilator treatment. This therapeutic approach may reduce the time on mechanical ventilation and the length of stay on an intensive care unit.

Kinetic therapy in the sense of the present invention is applied by use of specialized rotation beds which can be used in a continuous or a discontinuous mode with rests at any desired angle for a predetermined period of time. The general effect of axial rotation in respiratory insufficiency is the redistribution and mobilization of both intra-bronchial fluid (mucus) and interstitial fluid from the lower (dependent) to the upper (non-dependent) lung areas which will finally lead to an improved matching of local ventilation and perfusion. As a consequence, oxygenation increases while intra-pulmonary shunt decreases. Lymph flow from the thorax is enhanced by rotating the patient. In addition, rotation therapy promotes the recruitment of previously collapsed lung areas, thus reducing the amount of atelectasis. At the same time lung areas are protected from the shear stress typically caused by the repetitive opening and closing of collapse-prone alveoli in the dependent lung zones.

From H.-C. Pape, et al.: "Is early kinetic positioning beneficial for pulmonary function in multiple trauma patients?", Injury, Vol. 29, No. 3, pp. 219-225, 1998 it is known to use the kinetic therapy which involves a continuous axial rotation of the patient on a rotation bed. It has been found that the kinetic therapy improves the oxygenation in patients with impaired pulmonary function and with post-traumatic pulmonary insufficiency and adult respiratory distress syndrome (ARDS).

However, since the kinetic therapy requires a specially designed rotation bed it has not been found yet that the kinetic therapy justifies a broad employment.

It is an object of the invention to improve the potentials of the kinetic therapy.

This object is solved by a method and an apparatus for controlling at least one ventilation pressure of an artificial ventilator, by a method and an apparatus for determining the status of the lung of a patient lying in a rotation bed and by a method and an apparatus for controlling the rotation angle of a rotation bed.

A method according to the invention for controlling at least one ventilation pressure of an artificial ventilator for ventilating the lung of a patient lying in a rotation bed in accordance with a rotation angle of the rotation bed around its longitudinal axis comprises the following steps:

a) determining a first status of the artificially ventilated lung in accordance with a first rotation angle,

b) rotating the patient around its longitudinal axis to a second rotation angle,

c) determining a second status of the artificially ventilated lung in accordance with the second rotation angle, and

d) controlling the at least one ventilation pressure in accordance with the difference between the first status and the second status of the artificially ventilated lung.

A corresponding apparatus according to the invention for controlling at least one ventilation pressure of an artificial ventilator for ventilating the lung of a patient lying in a rotation bed in accordance with a rotation angle of the rotation bed around its longitudinal axis comprises:

a) means for determining a first status of the artificially ventilated lung in accordance with a first rotation angle,

b) means for rotating the patient around its longitudinal axis to a second rotation angle,

c) means for determining a second status of the artificially ventilated lung in accordance with the second rotation angle, and

d) means for controlling the at least one ventilation pressure in accordance with the difference between the first status and the second status of the artificially ventilated lung.

The inventive solution is based on the cognition that the top positioned lung during the rotation therapy is relieved which can be used for an optimised ventilation by an artificial ventilator. In order to reach the optimum of the at least one ventilation pressure during rotation, a second status of the artificially ventilated lung is determined and is compared with a previous determined first status of the artificially ventilated lung, wherein the at least one ventilation pressure is controlled in accordance with the difference between the first status and the second status of the artificially ventilated lung.

According to one aspect of the invention the determined status of the lung is sensitive to changes of alveolar dead space. The aim is to compensate the changes of alveolar dead space by a suitable adjustment of the positive end-expiratory pressure (PEEP) and peak inspiratory pressure (PIP). Various methods and apparatus are known for determining changes of alveolar dead space of an artificially ventilated lung which can be used separately or in combination with each other.

According to a further aspect of the invention the status of the lung is determined on the basis of the CO_2 concentration of the expired gas over a single breath. Such a method and apparatus are known from the previous European patent application "Non-Invasive Method and Apparatus for Optimizing the Respiration for Atelectatic Lungs", filed on 26 March 2004, which is herewith incorporated by reference.

According to a further aspect of the invention the status of the lung is determined on the basis of the hemoglobin oxygen saturation (SO_2). Such a method and apparatus are known from WO 00/44427 A1 which is herewith incorporated by reference.

According to a further aspect of the invention the status of the lung is determined on the basis of the CO_2 volume exhaled per unit time. Such a method and apparatus are known from WO 00/44427 A1 which is herewith incorporated by reference.

According to a further aspect of the invention the status of the lung is determined on the basis of the endtidal CO_2 concentration. Such a method and apparatus are known from WO 00/44427 A1 which is herewith incorporated by reference.

According to a further aspect of the invention the status of the lung is determined on the basis of the partial pressures of oxygen $paCO_2$. Such a method and apparatus are known from S. Leonhardt et al.: "Optimierung der Beatmung beim akuten Lungenversagen durch Identifikation physiologischer Kenngrößen", at 11/98, pp. 532 - 539, 1998 which is herewith incorporated by reference.

According to a further aspect of the invention the status of the lung is determined on the basis of the compliance of the lung, wherein the compliance can be defined by the lung volume devided by the pressure difference between peak inspiratory pressure and positive end-expiratory pressure (PIP - PEEP). Definitions of the compliance are known e.g. from WO 00/44427 A1 which is herewith incorporated by reference.

According to a further aspect of the invention the status of the lung is determined on the basis of electrical impedance tomography data. Such a method and apparatus are known from WO 00/33733 A1 and WO 01/93760 A1 which are herewith incorporated by reference.

According to a further aspect of the invention the at least one ventilation pressure is controlled such that the determined changes of alveolar dead space are compensated according to the difference between the first status and the second status of the artificially ventilated lung. For this purpose, a characteristic curve can be recorded for the corresponding lung showing the relationship between alveolar dead space on the one hand and the influence of peak inspiratory pressure (PIP) and positive end-expiratory pressure (PEEP) thereon on the other hand. Based on this characteristic curve the peak inspiratory pressure (PIP) and/or positive end-expiratory pressure (PEEP) can be determined for compensating any changes in alveolar dead space. In order to consider additionally the rotation angle by the characteristic curve, the status of alveolar dead space vs. PIP and/or PEEP has to be determined in accordance with the rotation angle of the rotation bed.

For this purpose, a method according to the invention for determining the status of an artificially ventilated lung of a patient lying in a rotation bed in accordance with a rotation angle of the rotation bed around its longitudinal axis comprises the following steps:

a) rotating the patient lying in a rotation bed by a step of a rotating angle around its longitudinal axis,

b) determining for a specific rotation angle the status of the artificially ventilated patient's lung, and

c) repeating steps a) and b) until the status of the artificially ventilated patient's lung has been determined over a predetermined range of rotation angles.

A corresponding apparatus according to the invention for determining the status of the lung of a patient lying in a rotation bed in accordance with a rotation angle of the rotation bed around its longitudinal axis comprises:

a) means for rotating the patient lying in a rotation bed by a step of a rotating angle around its longitudinal axis,

b) means for determining for a specific rotation angle the status of the artificially ventilated patient's lung, and

c) means for determining the status of the artificially ventilated patient's lung over a predetermined range of rotation angles.

For determining the status of the artificially ventilated lung all methods and apparatus as described above can be used.

The parameters of the controlling signal which controls the rotation angle of the rotation bed influences also the success of the kinetic therapy. An important parameter is the rotation period which is the period of time in which the rotation bed returns after a rotation in one direction back to its starting position. A further cognition of the invention is the fact that the success of the kinetic therapy can be improved if the rotation period is not fixed but varies statistically around a predetermined mean rotation period.

A corresponding method according to the invention for controlling the rotation angle of a rotation bed around its longitudinal axis comprises the following steps:

a) providing a periodical controlling signal having a predetermined distribution of a plurality of rotation periods,

b) controlling the rotation angle by said periodical controlling signal.

A corresponding apparatus for controlling the rotation angle of a rotation bed around its longitudinal axis comprises:

a) means for providing a periodical controlling signal having a predetermined distribution of a plurality of rotation periods,

b) means for controlling the rotation angle by said periodical controlling signal.

According to one aspect of the invention the distribution of the plurality of rotation periods can follow a Gaussian distribution.

According to a further aspect of the invention the distribution of the plurality of rotation periods can follow a biologic variability. For example, the human's heartbeat follows a characteristic biologic variability which can be scaled and adapted to provide for the described purpose.

Other objects and features of the invention will become apparent by reference to the following specification, in which

Fig. 1 shows a rotation bed according to the invention,

Fig. 2 shows the measurements of paO_2, $paCO_2$, and pHa during the kinetic therapy and

Fig. 3 shows the measurement of the compliance during the kinetic therapy.

Fig. 1 shows a rotation bed according to the invention. The rotation bed 100 is rotatable supported around its longitudinal axis. A controllable rotation motor 101 is provided for controlling the rotating action of the rotation bed. A measurement device 102 determines continuously the status of the patient's lung, for example by measuring the compliance.

The patient 105 is fixed on the rotation bed 100 and is artificially ventilated by the ventilator 104. A controlling unit 103 controls the rotation motor 101, evaluates the collected data of the measurement device 102 and controls the ventilation pressures of the ventilator 104.

The controlling of the rotation bed and the ventilator is carried out as follows:

<u>Recruitment Maneuver</u>

At 0° rotation angle PEEP is adjusted above the expected alveolar closing pressure (depending on the lung disease between 15 and 25 cmH_2O). PIP is set sufficiently high above PEEP to ensure adequate ventilation.

Then rotation is started.

With increasing rotation angle, a stepwise PIP increase starts 5 - 20 breath prior to reaching the maximum rotation angle, PIP reaches its maximum value (depending on the lung disease between 45 and 65 cmH_2O) at maximum rotation angle.

Having crossed the maximum angle PIP is decreased within 5 - 20 breaths.

After this recruitment, PIP is adjusted to maintain adequate ventilation.

PEEP Titration for Finding the Closing PEEP

After a recruitment maneuver, PEEP is decreased continuously with increasing rotation angles. The status of the artificially ventilated lung is recorded continuously.

At maximal rotation angle PEEP will be reduced by 1-2 cmH_2O. If no signs for alveolar collapse occur in any of the above signals the level of PEEP is recorded and reached the previous setting when at 0°. While turning the patient to the other side PEEP is reduced in the same way. If no signs for alveolar collapse occur in any of the above signals, the level of PEEP is then kept at this value and the patient is turned back to 0°.

Starting at this reduced PEEP level, the procedures 1 and 2 are carried out until signs for alveolar collapse occur in any of the above signals. The level of PEEP at which this collapse occurred is then recorded for the respective side and the lung is reopened in the way described above.

After having opened the entire lung again, the PEEP is set 2 cmH_2O above the known closing pressure for the one side.

Thereafter, PEEP is reduced in the way described above while turning the patient to the opposite side for which the closing pressure is not yet known. Once collapse occurs also for this side, PEEP is recorded and the lung is reopened again.

Controlling the Ventilation Parameters during Rotation

After having determined the PEEP collapse of each side, PEEP will be adjusted continuously with the ongoing rotation while making sure that PEEP never falls below the levels needed for each one of the sides.

Since PEEP and compliance may vary with the rotation angle adjustments are needed. Therefore, during rotation therapy PIP levels are adjusted continuously from breath to breath in accordance with the difference between a first status and a second status of the artificially ventilated lung in order to ventilate the patient sufficiently while keeping tidal volumes within a desired range of 6-10ml/kg body weight.

Furthermore, if PIP pressures are at very low values already, it might be advisible to leave PIP constant but adjust for changes in compliance by adjusting the respiratory rate (RR). Then, RR is adjusted continuously from breath to breath in order to ventilate the patient sufficiently while keeping PIP constant.

It has been shown that the variation of the rotation period improves the effect of the kinetic therapy even further. For example, the following modes of variation can be applied:

- Sinusoidal variation with wave length between several minutes to several hours with set minimum and maximum values for ration angles, speeds and resting periods.

- Ramp like variation within certain boundaries with ramp periods between several minutes to several hours and set minimum and maximum values for rotation angles, speeds and resting periods.

- Random variation about a given mean value at a single level of variability (i.e. biologic variability) with amplitudes between 50% to 200% of mean sequence of magnitude of this parameter from a uniform probability distribution between e.g. 0% to 100% of its chosen mean value.

- Variability can be determined according to technical approaches covering the whole range from allowed minimum to maximum.

- Distribution of rotation parameters can be Gaussian or biological.

In addition to the rotation period the rotation angle, the rotation speed and the resting periods can be varied. In order to adjust for variable rotation angles, speed and resting times, a mean product of angle and resting period etc can be defined, that needs to be kept constant. For example:

- While rotation angle randomly varies about a given rotation angle, resting periods are adjusted to keep the product of angle and time approximately constant at a given rotation speed.

- While rotation angle randomly varies about a given rotation angle, rotation speed is adjusted to keep the product of angle and speed approximately constant while no resting period is applied.

Fig. 2 shows the measurements of paO_2, $paCO_2$, and pHa during the kinetic therapy. As it can be seen, paO2 improves continuously during the kinetic therapy. The rotation period was switched from 8 to 16 rotation periods. Having a mean ventilation frequency of 10 to 40 ventilations per minute this results in 50 to 250 ventilations per rotation period.

Fig. 3 shows the measurement of the compliance during the kinetic therapy. As expected, the compliance improves during the kinetic therapy. As explained above, the ventilation parameters are adapted accordingly.

Claims

1. Method for controlling at least one ventilation pressure of an artificial ventilator for ventilating the lung of a patient lying in a rotation bed in accordance with a rotation angle of the rotation bed around its longitudinal axis, comprising the steps of:

   a) determining a first status of the artificially ventilated lung in accordance with a first rotation angle,

   b) rotating the patient around its longitudinal axis to a second rotation angle,

   c) determining a second status of the artificially ventilated lung in accordance with the second rotation angle, and

   d) controlling the at least one ventilation pressure in accordance with the difference between the first status and the second status of the artificially ventilated lung.

2. Method according to claim 1, wherein the determined status of the lung is sensitive to changes of alveolar dead space.

3. Method according to claim 2, wherein the status of the lung is determined on the basis of the CO_2 concentration of the expired gas over a single breath.

4. Method according to one of the claims 2 - 3, wherein the status of the lung is determined on the basis of the hemoglobin oxygen saturation (SO_2).

5. Method according to one of the claims 2 - 4, wherein the status of the lung is determined on the basis of the CO_2 volume exhaled per unit time.

6. Method according to one of the claims 2 - 5, wherein the status of the lung is determined on the basis of the endtidal CO_2 concentration.

7. Method according to one of the claims 2 - 6, wherein the status of the lung is determined on the basis of the partial pressures of oxygen $paCO_2$.

8. Method according to one of the claims 2 - 7, wherein the status of the lung is determined on the basis of the compliance of the lung.

9. Method according to one of the claims 2 - 8, wherein the status of the lung is determined on the basis of electrical impedance tomography data obtained from the lung.

10. Method according to one of the claims 2 - 9, wherein the at least one ventilation pressure is controlled such that the determined changes of alveolar dead space are compensated according to the difference between the first status and the second status of the artificially ventilated lung.

11. Method for determining the status of an artificially ventilated lung of a patient lying in a rotation bed in accordance with a rotation angle of the rotation

bed around its longitudinal axis, comprising the steps of:

a) rotating the patient lying in a rotation bed by a step of a rotating angle around its longitudinal axis,

b) determining for a specific rotation angle the status of the artificially ventilated patient's lung, and

c) repeating steps a) and b) until the status of the artificially ventilated patient's lung has been determined over a predetermined range of rotation angles.

12. Method for controlling the rotation angle of a rotation bed around its longitudinal axis, comprising the steps of:

a) providing a periodical controlling signal having a predetermined distribution of a plurality of rotation periods,

b) controlling the rotation angle by said periodical controlling signal.

13. Apparatus for controlling at least one ventilation pressure of an artificial ventilator for ventilating the lung of a patient lying in a rotation bed in accordance with a rotation angle of the rotation bed around its longitudinal axis, comprising:

a) means for determining a first status of the artificially ventilated lung in accordance with a first rotation angle,

b) means for rotating the patient around its longitudinal axis to a second rotation angle,

c) means for determining a second status of the artificially ventilated lung in accordance with the second rotation angle, and

d) means for controlling the at least one ventilation pressure in accordance with the difference between the first status and the second status of the artificially ventilated lung.

14. Apparatus according to claim 13, wherein the determined status of the lung is sensitive to changes of alveolar dead space.

15. Apparatus according to claim 14, wherein the status of the lung is determined on the basis of the CO_2 concentration of the expired gas over a single breath.

16. Apparatus according to one of the claims 14 - 15, wherein the status of the lung is determined on the basis of the hemoglobin oxygen saturation (SO_2).

17. Apparatus according to one of the claims 14 - 16, wherein the status of the lung is determined on the basis of the CO_2 volume exhaled per unit time.

18. Apparatus according to one of the claims 14 - 17, wherein the status of the lung is determined on the basis of the endtidal CO_2 concentration.

19. Apparatus according to one of the claims 14 - 18, wherein the status of the lung is determined on the basis of the partial pressures of oxygen $paCO_2$.

20. Apparatus according to one of the claims 14 - 19, wherein the status of the lung is determined on the basis of the compliance of the lung.

21. Apparatus according to one of the claims 14 - 20, wherein the status of the lung is determined on the basis of electrical impedance tomography data obtained from the lung.

22. Apparatus according to one of the claims 14 - 21, wherein the at least one ventilation pressure is controlled such that the determined changes of alveolar dead space are compensated according to the difference between the first status and the second status of the artificially ventilated lung.

23. Apparatus for determining the status of an artificially ventilated lung of a patient lying in a rotation bed in accordance with a rotation angle of the rotation bed around its longitudinal axis, comprising:

a) means for rotating the patient lying in a rotation bed by a step of a rotating angle around its longitudinal axis,

b) means for determining for a specific rotation angle the status of the artificially ventilated patient's lung, and

c) means for determining the status of the artificially ventilated patient's lung over a predetermined range of rotation angles.

24. Apparatus for controlling the rotation angle of a rotation bed around its longitudinal axis, comprising:

a) means for providing a periodical controlling signal having a predetermined distribution of a plurality of rotation periods,

b) means for controlling the rotation angle by said periodical controlling signal.

Abstract

The invention refers to a method and an apparatus for controlling at least one ventilation pressure of an artificial ventilator for ventilating the lung of a patient lying in a rotation bed in accordance with a rotation angle of the rotation bed around its longitudinal axis. For improving the potentials of the kinetic therapy a method according to the invention comprises the following steps:

a) determining a first status of the artificially ventilated lung in accordance with a first rotation angle,

b) rotating the patient around its longitudinal axis to a second rotation angle,

c) determining a second status of the artificially ventilated lung in accordance with the second rotation angle, and

d) controlling the at least one ventilation pressure in accordance with the difference between the first status and the second status of the artificially ventilated lung.

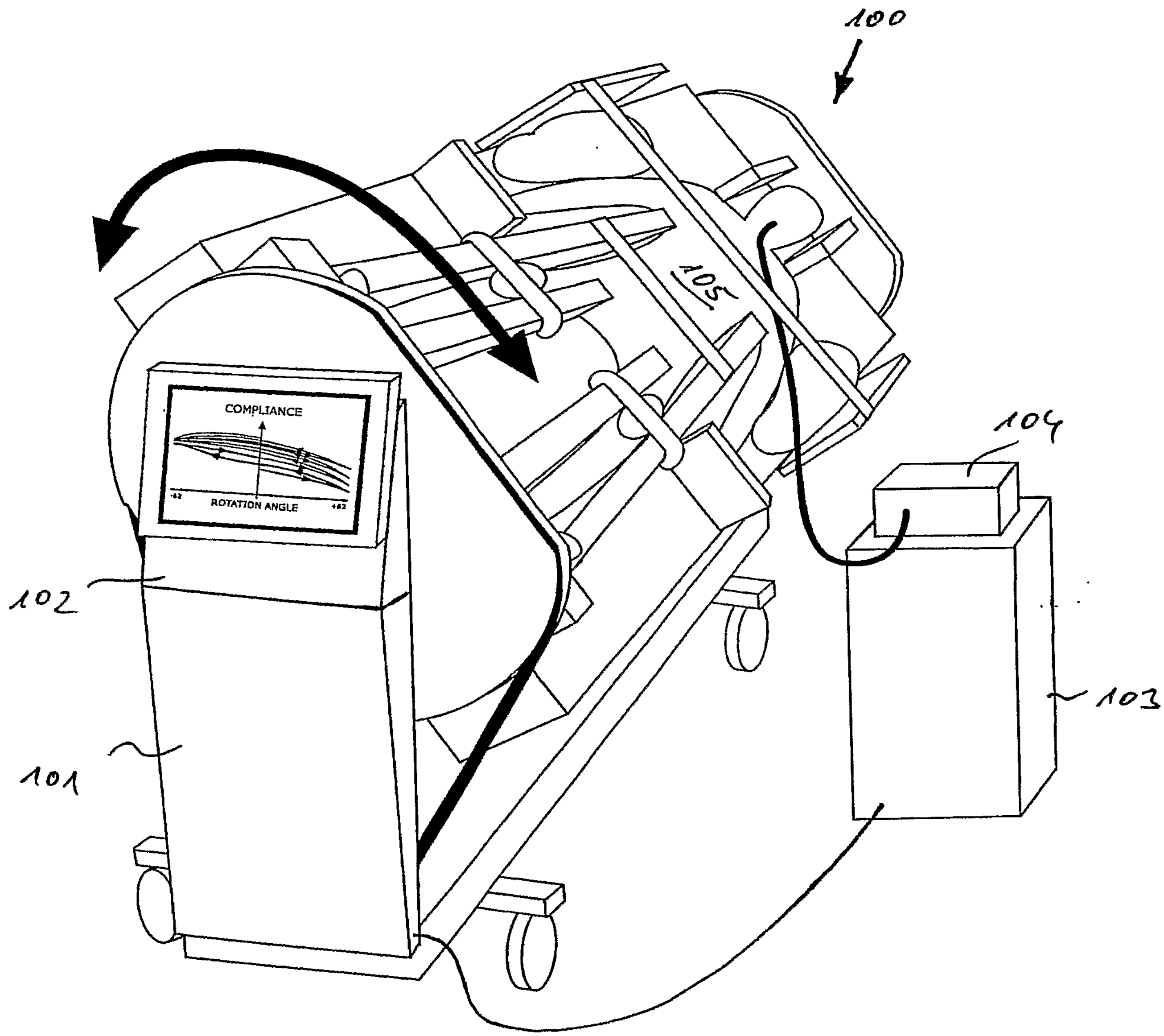

Fig. 1

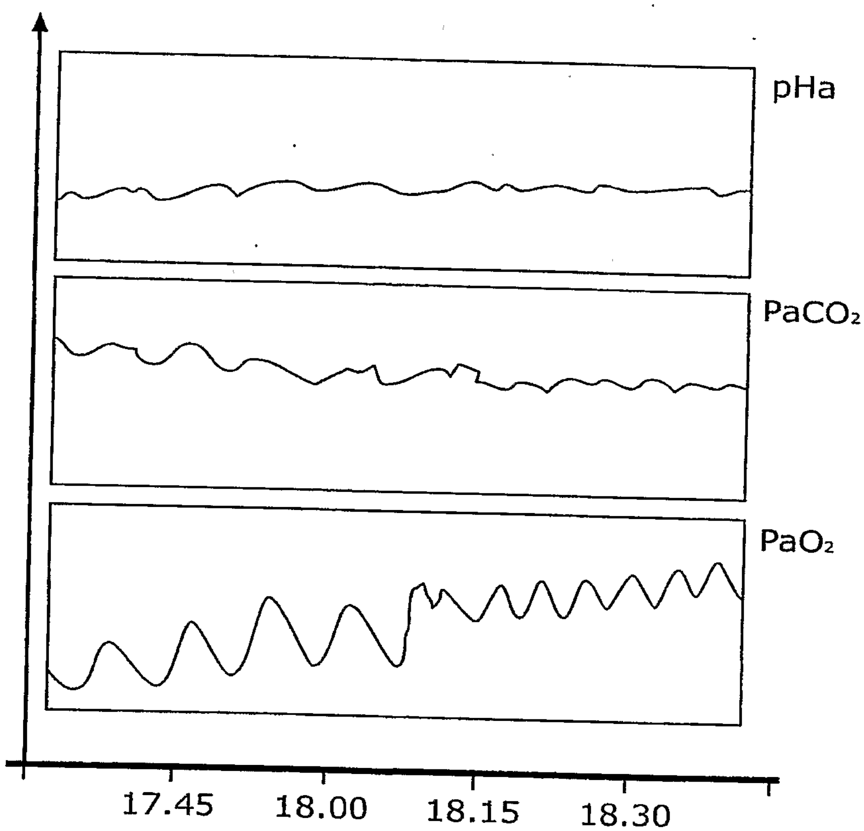

Fig. 2

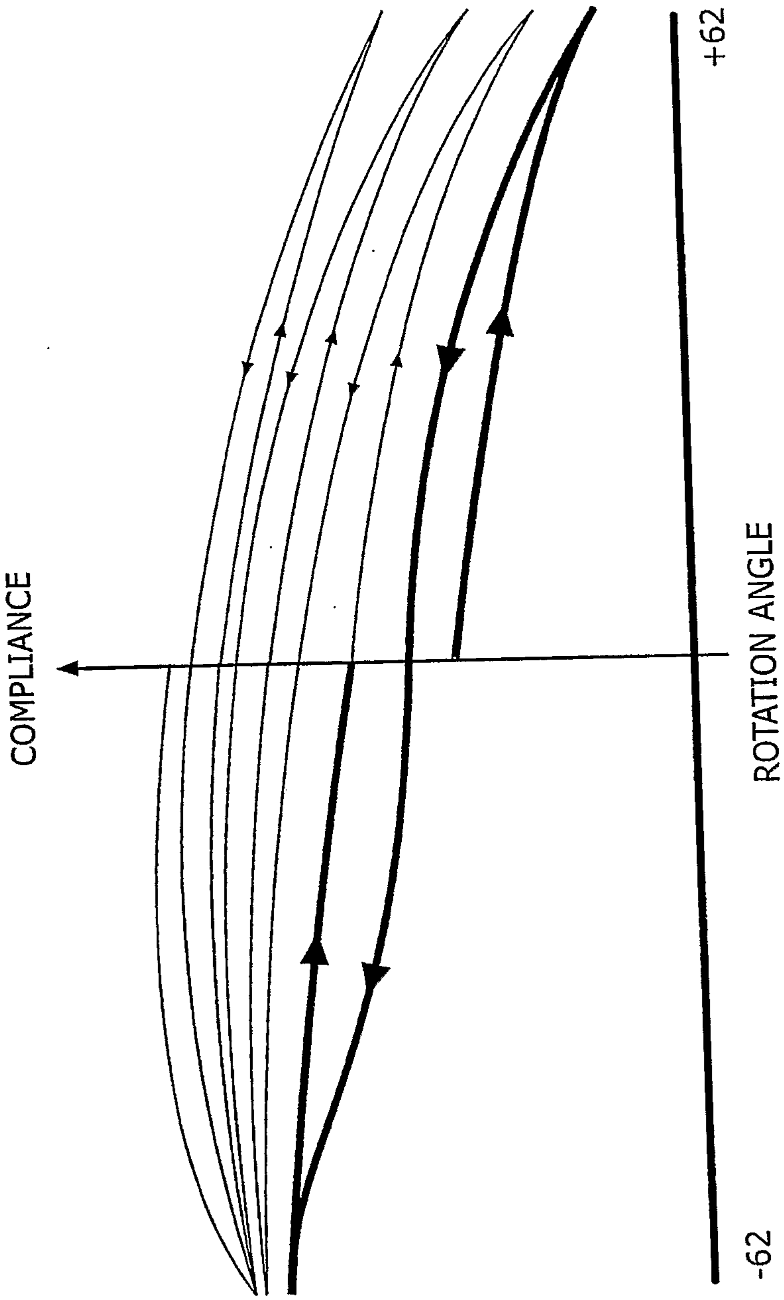

Fig. 3